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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,472	12/19/2005	Signe M. Christensen	63472(50533)	4416

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,472	CHRISTENSEN ET AL.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

Applicants' preliminary amendments to the claims, filed 5/17/05, are acknowledged. With entry of the amendment, Claims 1–42 are pending and subject to restriction as explained below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1–9, drawn to a pharmaceutical composition comprising a therapeutically active antisense oligonucleotide comprising at least one amino-LNA or derivative thereof. Election of this group requires the further election of a single composition, as explained below.

Group II, claim(s) 1–9, drawn to a pharmaceutical composition comprising a therapeutically active antisense oligonucleotide comprising at least one thio-LNA or derivative thereof. Election of this group requires the further election of a single composition, as explained below.

Group III, claim(s) 1–9, drawn to a pharmaceutical composition comprising a therapeutically active antisense oligonucleotide comprising at least two consecutive alpha-L-oxy-LNAs or derivatives thereof. Election of this group requires the further election of a single composition, as explained below.

Group IV, claim(s) 10–41, drawn to an oligonucleotide construct comprising one or more amino-LNAs or derivatives thereof, with the proviso that the oligo does not contain any of the constructs recited in claim 10. Election of this group requires the further election of a single construct, as explained below.

Group V, claim(s) 10–41, drawn to an oligonucleotide construct comprising one or more thio-LNAs or derivatives thereof, with the proviso that the oligo does not contain any of the constructs recited in claim 10. Election of this group requires the further election of a single construct, as explained below.

Group VI, claim(s) 42, drawn to a method of synthesis of a pharmaceutical composition or constructs. Election of this group requires the further election of a single composition or construct.

The inventions listed as Groups I–VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the products of Groups IV and V is an oligonucleotide construct comprising one or more amino- or thio LNAs, respectivel, or derivatives thereof, that does not contain any of the constructs recited in claim 10, which feature and/or lack of specific features are not required to be present or absent in any of groups I–III.

The special technical feature of Group III is an antisense oligonucleotide comprising at least two consecutive alpha-L-oxy-LNAs, which is not specifically required by Group I, II, or IV–VI.

The special technical features of each of Groups I, II, and III is an antisense oligonucleotide comprising an amino-LNA, thio-LNA, or at least two consecutive alpha-L-oxy-LNAs, respectively. Thus, each group requires a different special technical feature not required by the other.

The special technical feature of the methods of Group VI is a step (not recited but implicitly required) for synthesizing an oligonucleotide or pharmaceutical composition of Groups I–V, which feature is not present in any of the other groups.

Thus, unity of invention is lacking *a priori.*

Election of a single antisense oligonucleotide construct

Groups I–VI each contain claims directed to a multitude of different locked nucleic acid compositions and antisense oligonucleotides. Should applicant elect to prosecute any of these groups, Applicant must further elect a single chemically and structurally distinct antisense oligonucleotide thereof, as follows.

Altogether, claims 1–41 recite a vast number of different variants and combinations of the claimed LNAs.

Dependent claims 2, 4, 6, 11, 13, and 15, for example, recite several different alternatives of the claimed antisense oligonucleotides essential to the inventions of I–VI. This is not a complete listing of the claims to alternative constructs, only a sampling. Applicant is referred to claims 1–41 for complete review.

These compositions and oligonucleotides are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The special technical feature of each construct is the specific combination of chemical elements that must be present and/or absent in the molecule. Claims 2 and 11, for example, requires that the "B" unit have at least one nucleoside unit that has a 2'-deoxy-erythro-pentofuranosyl or a ribopentofuranosyl moiety. Claim 4 requires that the oligonucleotide have three adjacently located nucleotide sequences which may be in one of two different orders and may comprise locked and/or non-locked nucleotides, wherein B is one unit or sequence of units, with the proviso that B has at least one 2'-deoxy-erythro-pentofuranosyl or a ribopentofuranosyl moiety. Thus, the claims recite a number of alternative structures and compositions, each representing a different special technical feature.

Applicant is required, in reply to this action, to elect a single antisense oligonucleotide structure to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected structure, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Note: this is not a species election but an election of a single inventive concept.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional constructs which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected construct. MPEP § 809.02(a).

Applicant is specifically requested to elect a single chemically distinct construct of antisense oligonucleotide in as complete detail as recited in the instant claims for prosecution on the merits with the elected invention.

The following claim(s) are generic: 1 and 10 to the extent each recites a Markush-type alternative that is generic to the groups set forth above.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LVW
Art Unit 1635
April 16, 2007

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER